

R E M A R K S

Claims 1-30 are pending in the present application. The following rejections remaining at issue and are set forth by number in the order in which they are addressed:

1. Claims 1-30 are rejected under the judicially created doctrine of obviousness-type double patenting over claims 9-16 of U.S. Patent No. 6,015,833 in view of Cook et al. U.S. Patent No. 5,760,082; and
2. Claims 1-30 are rejected under 35 U.S.C. §103(a), as allegedly obvious over Cook et al. (U.S. Patent No. 5,760,082) in view of Cain et al. (WO97/18320) and Baltes et al. (U.S. 3,162,658) in further view of Nilsen et al. (U.S. 5,885,594);

Applicants believe that the amendments and remarks present herein traverse all of the Examiner's remaining rejections.

1. The Double Patenting Rejection Is Improper

Applicants contend that the double patenting rejection is not proper for the reasons stated in the prior Response and Amendment. Nevertheless, Applicants herein offer to submit a Terminal Disclaimer over the U.S. 6,015,833 upon the Examiner's indication of patentable subject matter in the instant application.

2. The Examiner Has Failed to Establish a *Prima Facie* Case of Obviousness

Claims 1-30 remain rejected under 35 U.S.C. §103(a) as allegedly being obvious under Cook et al. (U.S. Patent No. 5,760,082) in view of Cain et al. (WO97/18320) and Baltes et al. (U.S. 3,162,658) in further view of Nilsen et al. (U.S. 5,885,594) for the reasons made of record in the December 28, 2001, Office Action. Applicants must again respectfully disagree.

A *prima facie* case of obviousness requires the Examiner to cite a reference, or combination of references, that (a) discloses all of the elements of the claimed invention, (b) provides a suggestion or motivation to one of skill in the art to combine the elements to yield the claimed combination, and (c) provides a reasonable expectation of successfully carrying out the claimed combination. Failure to establish any one of the three requirements precludes a finding of a *prima facie* case of obviousness, and, without more, entitles the Applicants to allowance of the claims at issue.¹ In addressing this rejection, Applicants focus on the

¹ See, e.g., *Northern Telecom Inc. v. Datapoint Corp.*, 15 USPQ2d 1321, 1323 (Fed. Cir. 1990).

independent claims since the non-obviousness of independent claims necessarily leads to the non-obviousness of the claims dependent thereon.²

A. No Motivation To Combine The References

When applying 35 U.S.C. §103, the references must be considered as whole. References cannot be considered collectively until the Examiner points to some motivation to combine the cited references.³ Applicants submit that the Examiner has yet to provide sufficient evidence of a suggestion or motivation for making the cited combination. The Examiner states that:

Cook teaches a food product containing conjugated lineolic acids, Cain et al. teaches that it is well known in the art that antioxidants, such as vitamin E or BHT, is known to be useful in food products containing conjugated lineolic acid compounds Baltes teaches that isomerization of lineolic acid compounds to conjugated lineolic acid compounds by alcoholate catalysts. . . . Therefore, it would have been *prima facie* obvious to a person of ordinary skill in the art . . . to incorporate conjugated linoleic acid derivatives, including esters, as well as antioxidant in food product [sic].⁴

Simply reciting elements from the Cook and Cain references and then citing to Baltes et al., as allegedly providing suitable conjugation methods as used in the presently claimed invention is insufficient to establish a valid *prima facie* case of obviousness.

Cook et al. describe production of conjugated linoleic acids using KOH or NaOH and ethylene glycol (see e.g., *col. 2, ll. 20-27* and *col. 5, ll. 38-46*). However, there is NO suggestion in Cook et al., nor in any of the references, of **methods** for producing food products containing conjugated linoleic acid products wherein the compositions are derived from conjugated linoleic acid esters produced by treating the esters with an alcoholate catalyst as are presently being claimed.

Furthermore, when one examines the Baltes et al. reference, it is clear that there is no motivation to combine Cook, Cain, or Nilsen with Baltes to produce the presently claimed

² §MPEP 2143.03.

³ *Hodash v. Block Drug Co., Inc.*, 786 F.2d 1136, 1143, n. 5, 229 USPQ 182, 187, n.5 (Fed. Cir. 1986).

⁴ December 28, 2001, Office Action, *pp.* 3-4.

invention. In particular, Baltes et al. describe methods for producing conjugated linoleic acids described as being "valuable industrial products" for use in formation of "light colored polymers," for use as "ingredients of lacquers or coating compositions" or as "ingredients of plasticizers" and as "reaction components in the preparation of resins" (Baltes et al., *col. 9, ll. 47-60*). As such, the Baltes reference is directed to the production of substitutes for tung oil that are not suitable for consumption. The tung oil substitutes described in Baltes et al., are intended for industrial uses such as for drying oils, varnishes, and lacquers. Consequently, Baltes et al., describes methods for producing toxic oil substitutes for non toxic oils (tung oil). Nothing in the Baltes et al. reference teaches or suggest the desirability--or even applicability--of using the methods disclosed therein to produce food products.

Indeed, in view of the toxic products described in Baltes et al., the reference strongly **teaches away** from CLA compositions for suitable for oral consumption--let alone food products made by the claimed methods--even if viewed together with the other cited references.⁵ "A reference may be said to teach away when a person of ordinary skill, upon [examining] the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant."⁶

Accordingly, it is not proper to combine Baltes et al. with the other references because there is a lack of motivation for making this combination. This argument is supported by the previously submitted Declaration of Dr. Asgeir Sæbo. As detailed in the Sæbo Declaration,

⁵ Baltes et al. *col. 9, ll. 46-61* teach that:

The compounds of the conjugated fatty acids obtained by the method of this invention, or mixtures containing these compounds, are valuable industrial products which can be used in many ways. For instance their polymerisation by heating takes place at a very fast rate and therefore, the products can be converted into light colored polymer compounds by moderate heating, e.g., 260-280°C. The polymers thus formed can be used as ingredients of lacquers or coating compositions in conventional manner. Furthermore the conjugated fatty acids compounds of this invention can be used as ingredients of plasticizers for organic plastic materials, and as reaction components in the preparation of resins, such as alkyd resins or maleinate resins, in conventional manner.

⁶ *In re Para-Ordnance Manufacturing v. SGS Importers International*, 37 USPQ2d 1237, 1241 (Fed. Cir. 1995) (quoting *In re Gurley*, 31 USPQ2d 1130, 1131 (Fed. Cir. 1994).

none of the references teach or suggest using CLA isomerized with alcoholate catalysts in food products. Furthermore, as explained by Dr. Sæbo, the Baltes patent discloses the use of oils with high levels of triunsaturated fatty acids. These oils are not generally suitable for the production CLA for oral consumption. ✓

In the instant July 23, Final Office Action the Examiner again failed to provide evidence of a motivation or suggestion to combine the references, and in particular, to combine Baltes et al. with Cook, Cain, and Nilsen. The Examiner states that "Nowhere in Baltes [sic.] reference state that the method disclosed therein [sic.] only suitable for producing CLA solely for coating application [sic.]" Final Office Action, *p.* 4. The Examiner CANNOT contort the absence of a particular statement in a cited reference as somehow constituting evidence of that very same statement. Indulging in the Examiner's logic Applicants note that there would be an incentive for Examiner's to find a combination of references that are silent on a particular claim element and then force the Applicants to rebut a teaching that does not exist. The Examiner's arguments CANNOT stand under the Federal Circuit's precedent.

A recent Federal Circuit case explicitly discusses the standards for establishing motivation to combine. (*See, In re Lee*, 277 F.3d 1338 (Fed. Cir. 2002)). Specifically, the Federal Circuit held that:

The factual inquiry whether to combine references must be thorough and searching. It must be based on **objective evidence** of record. **This precedent has been reinforced in myriad decisions, and cannot be dispensed with.**⁷

Furthermore, an Examiner may not simply rely on conclusory statements even for what they think might be common sense or well known in the art:

The 'common knowledge and common sense' on which the Board relied in rejecting Lee's application are not the specialized knowledge and expertise contemplated by the Administrative Procedure Act. Conclusory statements such as those here provided do not fulfill the agency's obligation. This court explained in *Zurko*, 258 F.3d at 1385, 59 USPQ2d at 1697 that 'deficiencies of the cited references cannot be remedied by the Board's general conclusions about what is 'basic knowledge' or 'common sense.' The Board's findings must extend to all material facts and must be documented on record, lest the 'haze of so-called expertise' acquire insulation from accountability.

⁷ *See, In re Lee*, 277 F.3d 1338, 1344 (Fed. Cir. 2002); internal citations omitted; emphasis added.

'common knowledge and common sense,' even if assumed to derive from the agency's expertise, do not substitute for authority when the law requires authority.⁸

The majority of the claims pending in this application are method claims, not composition claims. Applicants note that the Examiner has apparently failed to take into consideration the fact the conjugated linoleic acid produced by the methods of the present invention differ in composition from other conjugated linoleic acid products. These differences are claimed, for example, in Claims 25-30 and described in the Specification at pages 18 and 19.

For the reasons stated above, Applicants respectfully submit that a *prima facie* case of obviousness has not been established and therefore respectfully request that this rejection be withdrawn.

B. References Do Not Teach All Of The Elements Of The Claims

In the their previous communications, Applicants argued that the references fail to teach all of the elements of the pending claims. In particular, the Applicants argued that none of the references teach or even suggest food products comprising conjugated linoleic acid moieties and an **alcohol**. Moreover, the references, even if combined, do not teach all of the elements of pending claims.

The Examiner's conclusory response in the July 23, 2002, Final Office Action to similar arguments made previously is that "CLA, vitamin E, and alcohol are known to be useful as food ingredients, the employment of the materials in food is such obvious [sic.], absent evidence to the contrary." (Final Office Action, *p.* 4). As Applicants stated above, they are not required to rebut statements that are unsupported. The Examiner cannot rest a case of *prima facie* obviousness on the premise that "absent evidence to the contrary" the Examiner's unsupported assertions are true and constitute evidence.

Applicants respectfully submit that the pending rejection should be withdrawn because the Examiner has failed to provide a sufficient evidentiary basis for the rejection as required by cases like *In re Lee*.

⁸ *Id.* at 1344-1345.

C. The Cited References Do Not Provide Reasonable Expectation Of Success

The cited references do not provide a reasonable expectation of successfully for obtaining the claimed methods and compositions.

The Federal Circuit has held that "obvious to experiment" is not the standard for obviousness.⁹ The Court in *In re Dow Chemical* made it very clear that one must determine whether "the prior art would have suggested to one of ordinary skill in the art that this process **should** be carried out and **would** have a reasonable likelihood of success, viewed in light of the prior art."¹⁰

Applicants submit that one skilled in the art would not believe that a reasonable expectation of success existed for arriving at the claimed invention. As described above, each of the claims contains the element of utilizing an alcoholate catalyst to produce conjugated linoleic acid. The conjugated linoleic acid is then used to produce a product for oral consumption such as a food product. As described in the Declaration of Dr. Asgeir Sæbo, one of skill in the art, upon reading the three cited references, would not conclude that CLA produced by the alcoholate catalysis method would be suitable for use in products meant for consumption. For example, Cook makes absolutely no reference to this method, and Baltes is solely directed to the production of conjugated fatty acids for industrial uses such as in varnishes and lacquers. Given this completely different use, a person skilled in the art would not conclude from the cited references that the alcoholate catalysis method would be suitable for use in the production of CLA meant for consumption. Therefore, the Examiner's use of Baltes to allegedly show the level of skill in the art is not dispositive.

While Baltes may show the level of skill in the art of producing drying oils for use in varnishes and lacquers, it does not show the level of skill in the art of nutrition and food products. The other cited references do not cure this deficiency. Accordingly, the references do not establish a reasonable expectation of success and a *prima facie* case of obviousness has not been established. The pending claims should be passed to allowance.

⁹ *In re Dow Chemical*, 5 USPQ2d 1529, at 1532 (Fed. Cir. 1988).

¹⁰ *Id.* at 1531; emphasis added.

3. The Declaration Of Dr. Asgeir Sæbo

The Examiner again states that the Declaration of Dr. Sæbo has been considered but found unpersuasive.¹¹ The Examiner's failure to accord Dr. Sæbo's Declaration due weight--without providing substantial contrary evidence--is not looked upon with favor by the Federal Circuit and does not conform with proper patent practice according the Manual of Patent Examining Procedure. The MPEP requires that:

Office personnel should consider all rebuttal arguments and evidence presented by applicants. . . . *In re Beattie*, 974 F.2d 1309, 1313, 24 USPQ2d 1040, 1042-43 (Fed. Cir. 1992). . . . **Office personnel should avoid giving evidence no weight**, except in rare circumstances. *Id.* See also *In re Alton*, 76 F.3d 1168, 1174-75, 37 USPQ2d 1578, 1582-83 (Fed. Cir. 1996).

* * *

A determination under 35 U.S.C. 103 should rest on **all the evidence** and should not be influenced by any earlier conclusion. See, e.g., *Piasecki*, 745 F.2d at 1472-73, 223 USPQ at 788; *In re Eli Lilly & Co.*, 902 F.2d 943, 945, 14 USPQ2d 1741, 1743 (Fed. Cir. 1990). Thus, once the applicant has presented rebuttal evidence, Office personnel should **reconsider** any initial obviousness determination in view of the entire record. See, e.g., *Piasecki*, 745 F.2d at 1472, 223 USPQ at 788; *Eli Lilly*, 902 F.2d at 945, 14 USPQ2d at 1743.¹²

Additionally, the Courts have held as follows:

When *prima facie* obviousness is established and evidence is submitted in rebuttal, the decision-maker must start over An earlier decision should not . . . be considered as set in concrete, and applicant's rebuttal evidence then be evaluated only its knockdown ability. Analytical fixation on an earlier decision can tend to provide the decision with an undeservedly broadened umbrella effect. *Prima facie* obviousness is a legal conclusion, not a fact. Facts established by rebuttal evidence must be evaluated along with the facts on which the earlier conclusion was reached, not against the conclusion itself. Though the tribunal must begin anew, a final finding of obviousness may of course be reached, but such finding will rest upon evaluation of all facts in evidence, uninfluenced by any earlier conclusion reached . . . upon a different record.¹³

The Examiner's statement in the July 23, 2002, Final Office Action that "sufficient contrary evidence" was provided for not giving the Sæbo Declaration its due weight in view of the citation to the Baltes reference is noted. However, Applicant's respectfully submit that the

¹¹ Office Action, p. 5.

¹² MPEP §§2144.08; emphasis added).

¹³ *In re Rinehart*, 531 F.2d 1048, 1052, 189 USPQ 143, 147 (CCPA 1976).


remarks made above distinguishing the Baltes reference underscore the Examiner's failure to provide sufficient evidence that contradicts the Sæbo Declaration.

Accordingly, in view of un rebutted fact based Declaration of Dr. Sæbo, the Examiner should withdraw this rejection and pass the pending claims to allowance.

C O N C L U S I O N

All grounds of rejection and objection of the Final Office Action of July 23, 2002, having been addressed, reconsideration of the application is respectfully requested. It is respectfully submitted that the invention as claimed fully meets all requirements and that the claims are worthy of allowance. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicant encourages the Examiner to call the undersigned collect at (608) 218-6900.

Dated: September 23, 2002


Thomas J. Borner
Registration No. 47,436

MEDLEN & CARROLL, LLP
101 Howard Street, Suite 350
San Francisco, California 94105

APPENDIX 1
Clean Version Of The Entire Set Of Pending Claims

1. (Amended once) A method for producing a food product containing conjugated linoleic acid esters comprising:
 - a) providing:
 - i) linoleic acid esters,
 - ii) an alcoholate catalyst,
 - iii) a foodstuff;
 - b) treating said linoleic acid esters with said alcoholate catalyst to provide conjugated linoleic acid esters; and
 - c) combining said foodstuff with said conjugated linoleic acid esters to produce a food product.
2. The method of Claim 1, wherein said linoleic acid esters are derived from oils selected from the group consisting of safflower, sunflower, and corn oil.
3. (Amended once) The method of Claim 1, wherein said alcoholate catalyst is selected from the group consisting of sodium methylate, potassium methylate, sodium ethylate, and potassium ethylate.
4. (Amended Once) The method of Claim 1, further comprising providing an antioxidant and combining said antioxidant with said conjugated linoleic acid esters and said foodstuff in step (b) to produce said food product.
5. (Amended Once) The method of Claim 4, wherein said antioxidant is selected from the group consisting of α -tocopherol, β -tocopherol, lecithin, ascorbylpalmitate, and BHT.
6. (Amended Twice) The food product produced according to the method of Claim 1, further comprising an antioxidant selected from the group consisting of lecithin, ascorbylpalmitate, and BHT.

7. (Amended Twice) A method for producing a food product containing conjugated linoleic acid comprising:

- a) providing:
 - i) linoleic acid esters,
 - ii) an alcoholate catalyst,
 - iii) a foodstuff;
 - b) treating said linoleic acid esters with said alcoholate catalyst to provide conjugated linoleic acid esters;
 - c) treating said conjugated linoleic acid esters to provide conjugated linoleic acid;
- and
- d) combining said foodstuff with said conjugated linoleic acid to produce a food product.

8. The method of Claim 7, wherein said linoleic acid esters are derived from oils selected from the group consisting of safflower, sunflower, and corn oil.

9. (Amended once) The method of Claim 7, wherein said alcoholate catalyst is selected from the group consisting of sodium methylate, potassium methylate, sodium ethylate, and potassium ethylate.

10. (Amended Once) The method of Claim 7, further comprising providing an antioxidant and combining said antioxidant with said conjugated linoleic acid and said foodstuff in step (b) to produce said food product.

11. (Amended Once) The method of Claim 10, wherein said antioxidant is selected from the group consisting of α -tocopherol, β -tocopherol, lecithin, ascorbylpalmitate, and BHT.

12. (Amended Twice) The food product produced according to the method of Claim 7, further comprising an antioxidant selected from the group consisting of lecithin, ascorbylpalmitate, and BHT.

13. (Amended Once) A method for producing a food product containing conjugated linoleic acid triglycerides comprising:
- a) providing:
 - i) linoleic acid esters,
 - ii) an alcoholate catalyst, and
 - iii) a foodstuff; and
 - b) treating said linoleic acid esters with said alcoholate catalyst to provide conjugated linoleic acid esters;
 - c) incorporating said linoleic acid esters into triglycerides to provide triglycerides containing conjugated linoleic acid moieties; and
 - d) combining said foodstuff with said triglycerides containing conjugated linoleic acid moieties to produce a food product.
14. The method of Claim 13, wherein said linoleic acid esters are derived from oils selected from the group consisting of safflower, sunflower, and corn oil.
15. (Amended once) The method of Claim 13, wherein said alcoholate catalyst is selected from the group consisting of sodium methylate, potassium methylate, sodium ethylate, and potassium ethylate.
16. (Amended Once) The method of Claim 13, further comprising providing an antioxidant and combining said antioxidant with said triglycerides and said foodstuff in step (b) to produce said food product.
17. (Amended Once) The method of Claim 16, wherein said antioxidant is selected from the group consisting of α -tocopherol, β -tocopherol, lecithin, ascorbylpalmitate, and BHT.
18. (Amended Twice) The food product produced according to the method of Claim 13, further comprising an antioxidant selected from the group consisting of lecithin, ascorbylpalmitate, and BHT.

19. (Amended Once) A method for producing a food product comprising:
- a) providing:
 - i) linoleic acid esters;
 - ii) an alcoholate catalyst; and
 - iii) a foodstuff;
 - b) producing a conjugated linoleic acid esters by treating said linoleic acid esters with said alcoholate catalyst; and
 - c) combining said conjugated linoleic acid esters with said foodstuff to produce a food product.
20. The method of Claim 19, wherein said linoleic acid esters are derived from oils selected from the group consisting of safflower, sunflower, and corn oil.
21. (Amended once) The method of Claim 19, wherein said alcoholate catalyst is selected from the group consisting of sodium methylate, potassium methylate, sodium ethylate, and potassium ethylate.
22. The method of Claim 19, further comprising providing an antioxidant and combining said antioxidant with said conjugated linoleic acid esters and said foodstuff in step (c) to produce said food product.
23. (Amended Once) The method of Claim 22, wherein said antioxidant is selected from the group consisting of α -tocopherol, β -tocopherol, lecithin, ascorbylpalmitate, and BHT.
24. (Amended Twice) The food product produced according to the method of Claim 19, further comprising an antioxidant selected from the group consisting of lecithin, ascorbylpalmitate, and BHT.
25. A food product comprising a conjugated linoleic acid moiety and an alcohol.

26. The food product of Claim 25, wherein said alcohol is ethyl alcohol.
27. The food product of Claim 25, wherein said alcohol is present in a concentration of about less than 10 ppm.
28. The food product of Claim 25, wherein said conjugated linoleic acid moiety is an ester of conjugated linoleic acid.
29. The food product of Claim 25, wherein said conjugated linoleic acid moiety is a free fatty acid.
30. The food product of Claim 25, wherein said conjugated linoleic acid moiety is a triglyceride.